



AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 228

RIN 0412-AB02

Procurement of Certain Essential Medical Supplies to Address the Covid-19 Pandemic

AGENCY: Agency for International Development.

ACTION: Temporary final rule.

SUMMARY: The United States Agency for International Development (USAID) is issuing a Temporary Final Rule (TFR) amending [our regulations](#) to allow USAID to waive “Source and Nationality” rules to provide for increased flexibility, targeting, and speed of procurement of Essential Medical Supplies (EMS) required to address the COVID-19 pandemic worldwide.

DATES: *Effective date:* This rule is effective October 23, 2020 through April 30, 2021.

ADDRESSES: You may review the docket by searching for Docket ID [AID-2020-0004], via the Federal eRulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A. The Current COVID-19 Pandemic in the United States

Coronavirus Disease 2019 (COVID-19) is a highly communicable infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). On January 30, 2020, the Director-General of the World Health Organization (WHO) declared the outbreak of COVID-19 a Public Health Emergency of International Concern under the International Health Regulations. On January 31, 2020, the HHS Secretary declared COVID-19 a Public Health Emergency under Section 319 of the Public Health Service (PHS) Act, [42 U.S.C. 247d](#). On March 11, 2020, the WHO declared the COVID-19 outbreak a pandemic. On March 13, 2020, the President issued a declaration of a national emergency under Sections 201 and 301 of the National Emergencies Act, [50 U.S.C. 1601-1651](#), and consistent with Section 1135 of the Social Security Act, [42 U.S.C. 1320b-5](#). See [Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease \(COVID-19\) Outbreak](#).

On March 13, 2020, the President also declared a nationwide emergency under Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, [42 U.S.C. 5121-5207](#) (the “Stafford Act”), authorizing FEMA to provide assistance for emergency protective measures to respond to the COVID-19 pandemic. Under the Stafford Act, FEMA may direct USAID, through a Mission Assignment, to use its authorities and resources to meet domestic needs, including making available any EMS to FEMA.

As of May 21, 2020, there were over 1.5 million confirmed cases of COVID-19 in the United States, resulting in over 93,000 deaths due to the disease, with new cases and fatalities being reported daily. Worldwide, there have been over 5 million confirmed cases, resulting in over 328,000 deaths. Presently, there is no vaccine that can prevent infection with COVID-19, nor is there currently any FDA-approved post-exposure prophylaxis for people who may have been exposed to COVID-19. Treatment is limited to supportive (or palliative) care for patients who need it. Clinical management for hospitalized patients with COVID-19 is focused on supportive care for complications, including supplemental oxygen and advanced organ support for respiratory failure, septic shock, and multi-organ failure.

B. USAID's Response to COVID-19

USAID is responding to the COVID-19 pandemic with decisive action at home and abroad. Our priorities in the response are to protect the safety and health security of our global workforce, ensure that we can continue our life-saving mission across the world, and support partner countries in their response to COVID-19.

USAID, together with the Department of State, launched the Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad. Under Pillar 2 of this Strategy, USAID addresses three components - the emergency health response, strengthening health security capacities in affected countries, and helping to rebuild health systems as part of addressing the second order health effects of the pandemic. As of April 24, the USAID Bureau for Global Health (GH), in response to the pandemic, obligated \$99 million from the Emergency Reserve Fund for Infectious Disease Outbreaks, and another approximately \$90 million of the

total \$435 million Global Health Programs COVID-19 supplemental. GH programming has focused on the following technical areas: risk communication and community engagement; surveillance, rapid response teams, and contact tracing; port of entry; infection prevention and control; laboratory systems; case management; and response operations and coordination. The provision of commodities is critical for the laboratory systems, case management, and infection prevention and control components. Under Pillar 3 of the Strategy, USAID will prevent, prepare for, and respond to COVID-19 in existing complex emergency responses and address potential humanitarian consequences of the pandemic. Further, under Pillar 4 of the Strategy, USAID will prepare for, mitigate and address second order economic, civilian security, stabilization, and governance effects of COVID-19. The provision of commodities will be components of these activities. In total, USAID estimates that approximately \$137 million may be used for providing Essential Medical Supplies for overseas use.

C. Authorities

USAID is issuing this temporary final rule as part of its response to the COVID-19 pandemic. The Administrative Procedure Act (“APA”) generally requires an agency to publish a notice of proposed rulemaking in the Federal Register and provide an opportunity for public comment. This requirement does not apply, however, if the agency “for good cause finds... that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” [5 U.S.C. 553\(b\)\(3\)\(B\)](#). The APA also generally requires that an agency publish an adopted rule in the Federal Register at least 30 days before it becomes effective. This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner. [Section 553\(d\)\(3\)](#).

The rates of COVID-19 infections and the number of deaths caused by COVID-19 are significantly increasing on a daily basis worldwide. The demand for EMS is increasing worldwide given the rising number of infections. Second and possibly third waves are expected according to the medical experts. The courts have recognized that concern for public safety can constitute good cause to bypass notice and comment procedures. (See, *Jifry v. F.A.A.*, 370 F.3d 1174, 1179-80 (D.C. Cir. 2004). The courts have further found that immediate threats to human life and physical security typically constitute an important enough interest to justify use of the good cause exception. (See, *Hawaii Helicopter Operators Ass'n v. Federal Aviation Administration*, 51 F.3d 212 (9th Cir. 1995). This rule is intended to help protect the public from this immediate health threat by providing USAID increased flexibility, targeting, and speed of procurement of EMS required to address the COVID-19 pandemic worldwide. Given the temporary nature of this rule, its narrow application to EMS, and the significant and immediate threat to public health and safety in the United States and worldwide, the Agency finds that this emergency is sufficiently compelling to constitute good cause to forgo notice and comment. It would be contrary to the interest of public health and contrary to our national security and foreign policy interests to delay this rule.

The rule is issued accordance with section 604 of the Foreign Assistance Act (FAA) of 1961, as amended, [22 U.S.C. 2354](#).

Under the authority of the FAA and the APA, USAID issues this temporary final rule.

II. Provisions of Temporary Final Rule

USAID is working directly with governments, multilateral organizations, NGOs, the private sector, and other organizations responding on the ground to combat this dangerous pathogen. This includes working with front-line workers to slow the spread, care for those affected by, and equip local communities with the tools needed to fight back against COVID-19. Pandemics know no borders, and therefore international cooperation is vital. We will not successfully defeat this pandemic threat, and avoid a second or third wave, unless we fight it around the world. That is why our approach must include the necessary tools and resources to protect the safety and interests of Americans and ensure the United States continues to lead on the global response. The United States industry is uniquely positioned to produce EMS to support the achievement of COVID-19 domestic and international objectives. USAID's primary reliance on these sources ensures the availability of these critical supplies to assist countries affected by COVID-19. This temporary final rule allows flexibility to ensure those in need around the world will have access to lifesaving EMS to address COVID-19 when and where they need it. The measures described in this rule are being issued on a temporary basis from October 23, 2020 through April 30, 2021.

Current regulations authorize the following:

[22 CFR 228.03\(a\)](#) authorizes purchases from Geographic Code 937, which is defined as the United States, the cooperating/recipient country, and developing countries other than advanced developing countries, and excluding prohibited sources.

It further allows for certain purchases from Geographic Code 935, which is defined as any area or country except prohibited countries, based on additional statutory authority or otherwise approved via a waiver in accordance with Subpart D. [Section 228.03\(b\)](#).

For purchases under Support for Economic and Democratic Development of the Independent States of the Former Soviet Union, [§ 228.03\(c\)](#), the authorized principal geographic codes are Code 937 and Code 110 (New Independent States).

Under the current provisions of 22 CFR part 228, USAID only has the authority to expand the authorized geographic scope under the waiver provisions. The temporary final rule allows USAID to prioritize the purchase of EMS: from the United States only, from the cooperating/recipient country, from the geographic region to avoid diverting supplies in short supply in the United States, or from a nearby country. “Nearby country” means any bordering country or any country that is in the same geographical region as the country receiving assistance, as defined by the Department of State’s regional system (i.e., [Africa](#); [East Asia and Pacific](#); [Europe and Eurasia](#); [Near East](#); [South and Central Asia](#); [Western Hemisphere](#)).

However, if, as determined by USAID on a case-by-case basis, EMS is unavailable from the United States, the cooperating/recipient country, and a nearby country; or is unavailable in sufficient, reasonable, and available quantities, or sufficient and reasonable quality that is fit for the intended purpose, procurement from Code 935 is authorized.

III. Temporary Changes to 22 CFR Part 228

The below changes will remain in effect until October 23, 2020 through April 30, 2021.

[22 CFR 228.11](#) is being amended to require implementing partners to receive approval from USAID before purchasing EMS. This will allow USAID to issue a waiver for the purchase of EMS from the United States only, from the cooperating/recipient country, from specific geographic region, or from a nearby country.

[22 CFR 228.30](#) is being amended to add subsection (e) which allows waivers to geographic areas necessary for the purchase of EMS to address the COVID-19 pandemic. For example, it authorizes purchases from the United States only, or from nearby countries that may not be included in Geographic Code 937. It also authorizes purchases from the cooperating/recipient country or from certain geographic areas when there are shortages in the United States. The Agency plans to issue a waiver to prioritize geographic areas for the purchase of EMS to address the COVID-19 pandemic.

IV. Regulatory Considerations and Determinations

A. Executive Orders 12866 and 13563

Executive Orders [12866](#) and [13563](#) direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). [Executive Order 13563](#) emphasizes the importance of

quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of [Executive Order 12866](#) defines a “significant regulatory action” as an action that is likely to result in a regulation (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary effects of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

This rule change narrowly applies to EMS purchased to address the COVID-19 pandemic. The estimated amount of funding potentially affected is approximately \$137 million. Buying from the United States only would positively affect the United States economy and help development of our manufacturing capacity to respond to future crises. USAID’s foreign assistance mandate is unchanged. This rule has been designated a “significant regulatory action,” but not “economically significant,” under Section 3(f) of [Executive Order 12866](#). This rule has been reviewed by the Office of Management and Budget.

B. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a 'major rule', as defined by 5 U.S.C. 804(2).

C. Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), [5 U.S.C. 601-612](#), USAID has considered the economic effect of the Temporary Final Rule and has certified that its provisions would not have a significant economic effect on a substantial number of small entities.

D. Paperwork Reduction Act

There is no reporting or documentation or other information collection requirements under the Final Rule that require analysis under the Paperwork Reduction Act. [44 U.S.C. 3501-3583](#).

List of Subjects in 22 CFR Part 228

Government procurement.

For the reasons discussed in the preamble, USAID amends 22 CFR part 228 as set forth below:

PART 228 - RULES FOR PROCUREMENT OF COMMODITIES AND SERVICES FINANCED BY USAID

1. The authority citation for 22 CFR part 228 continues to read as follows:

Authority: Sec. 621, Pub. L. 87-195, 75 Stat. 445 (22 U.S.C. 2381), as amended, E.O. 12163, Sept. 29, 1979, 44 FR 56673; 3 CFR 1979 Comp., p. 435.

2. Revise § 228.01 to read as follows:

§228.01 Definitions.

Essential medical supplies means personal protective equipment, medical products and equipment, pharmaceuticals, and other medical countermeasures needed to address the COVID-

19 pandemic, which are in short supply, as identified in the “Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures” issued by the Department of Health and Human Services (HHS) on March 25, 2020, as updated. USAID may designate additional materials as “emergency medical supplies” if deemed necessary and will publish notice of these additional materials in the Federal Register.

3. Revise § 228.11 to read as follows:

§ 228.11 Source of commodities.

The source of all commodities financed with Federal program funds appropriated under the Foreign Assistance Act of 1961, as amended, shall be Code 937 (unless Code 935 or 110 are designated in the implementing instrument), except for essential medical supplies purchased to address the COVID-19 pandemic, the source of which must be approved by USAID prior to purchase unless otherwise directed by USAID. Procurements of agricultural commodities, motor vehicles, and pharmaceuticals must also comply with the special procurement rules in § 228.19. Recipients and contractors are prohibited from engaging suppliers of commodities in an authorized country to import commodities from a country outside of the authorized principal geographic codes for the purposes of circumventing the requirements of this rule. Any violation of this prohibition will result in the disallowance by USAID of the cost of the procurement of the subject commodity.

4. Revise § 228.30 to read as follows:

§ 228.30 General.

USAID may waive the rules contained in subparts A, B, and C of this part (except for prohibited sources as defined in § 228.01, and §§ 228.21 and 228.22), in order to accomplish project or program objectives. Except for paragraph (e) of this section, for any waivers authorized, the principal geographic code shall be Code 935, any area or country but excluding prohibited sources. All waivers must be in writing, and where applicable, are limited to the term established by the waiver. All waiver decisions will be made solely on the basis of the following criteria:

(a) Waivers to permit procurement outside of Code 937 or 110 must be based on a case by case determination that:

(1) The provision of assistance requires commodities or services of the type that are not produced in and available for purchase in Code 937 or 110;

(2) It is important to permit procurement from a country not specified in Code 937 or 110 to meet unforeseen circumstance; or

(3) To promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives.

(b) Case by case waivers under paragraph (a) of this section may be made on the basis of a commodity or service type or category, rather than processing repeat, individual waivers for an identical or substantially similar commodity or service. Such waivers may be approved on a regional, country, or program basis. For purposes of paragraph (a)(1) of this section, “produced in and available for purchase in” shall have the same meaning as the definition of “available for purchase” in § 228.01. A waiver under paragraph (a)(1) of this section may also be based on the fact that a commodity is not available for purchase in Code 937 or 110 in sufficient, reasonable, and available quantities or sufficient and reasonable quality that is fit for the intended purpose.

(c) A waiver to authorize procurement from outside the United States of agricultural commodities, motor vehicles, and pharmaceuticals must meet the requirements of § 228.19.

(d) Any individual transaction not exceeding \$25,000 (excluding essential medical supplies purchased to address the COVID-19 pandemic), excluding those covered by special procurement rules in § 228.19, and excluding procurements from prohibited sources) does not require a waiver and is hereby authorized.

(e) For purchases of essential medical supplies to address the COVID-19 pandemic, waivers shall be authorized to the United States only, to the cooperating/recipient country, and/or to a nearby country. Nearby country means any bordering country or any country that is in the same geographical region as the country receiving assistance, as defined by the Department of State's regional system. If, as determined by USAID on a case by case basis, essential medical supplies are unavailable from the United States, the cooperating/recipient country, and a nearby country, or are unavailable in sufficient, reasonable, and available quantities or sufficient and reasonable quality that is fit for the intended purpose, procurement from Code 935 is authorized.

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[FR Doc. 2020-16475 Filed: 10/22/2020 8:45 am; Publication Date: 10/23/2020]